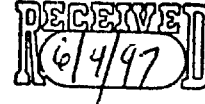




901 E. 233rd Street
Carson, California
90745-6204
310/835-8400
Fax 310/835-6615

May 27, 1997

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street S.W.
Washington, D.C. 20204



0163 '97 SEP 19 P1:45

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **LEINER HEALTH PRODUCTS** notifies the FDA that it has begun using the following phrase and statements:

Specifically, you may find yourself more concerned about undesirable cardiovascular changes, maintaining sharp mental and visual acuity, and maintaining male vigor and prostate health.

(Multi-Vitamin and Minerals) The minerals in this formula are helpful for a healthy nervous system and a healthy heart.

(Multi-Vitamin and Minerals) Selenium has been the subject of important recent research, indicating many promising health benefits.

(Multi-Vitamin and Minerals) Saw Palmetto, a traditional herb, has been included because it is believed to contribute to male health and balance.

(Natural Vitamin E) Vitamin E is required for the healthy formation of red blood cells and has a positive effect on cardiovascular health.

(Natural Vitamin E) It also appears to have a positive effect on protein metabolism, fat metabolism and hormone function.

(Calcium) It also helps maintain a healthy heart.

(Ginkgo Biloba) Ginkgo Biloba is traditionally used for its ability to enhance mental alertness and cerebral blood flow.

975-0162

LET 669
52901



Office of Special Nutritionals (HFS-450)

May 27, 1997

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The above statements are being made on the following product:

Nature's Code™ For Men Over 50

Very truly yours,

LEINER HEALTH PRODUCTS

A handwritten signature in cursive script, appearing to read "Gale Bensussen", written over a horizontal line.

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs
William Cochran, Regulatory Affairs